



DOCKET NO.: 211892US0PCT

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 09/913,720

Applicants: Hans-Ulrich PETEREIT et al

Filing Date: August 31, 2001

For: INJECTION MOLDING METHOD FOR NEUTRAL  
AND ACIDIC-GROUP CONTAINING (METH)  
ACRYLATE COPOLYMERS

Group Art Unit: 1615

Examiner: Robert JOYNES

SIR:

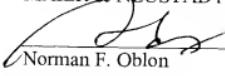
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**PTO COVER LETTER  
APPEAL BRIEF (IN TRIPPLICATE)**

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Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

  
Norman F. Oblon

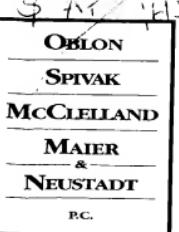
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Hans-Ulrich PETEREIT et al.

SERIAL NO.: 09/913,720

FILED: August 31, 2001

FOR: INJECTION MOLDING METHOD FOR NEUTRAL  
AND ACIDIC-GROUP CONTAINING (METH) ACRYLATE  
COPOLYMERS



: GROUP ART UNIT: 1615

: EXAMINER: Robert JOYNES

APPEAL BRIEF

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Appellants appeal the final rejection of Claims 1-8, 10 and 11 of the above-identified application set forth in the final Official Action dated August 26, 2003.

I. REAL PARTY IN INTEREST

The real party in interest is Roehm GMBH & Co. KG by virtue of the Assignment executed on November 19, 2001. The executed Assignment was forwarded to the U.S. Patent and Trademark Office and recorded on November 19, 2001.

II. RELATED APPEALS AND INTERFERENCES

To the best of Appellants' undersigned representative's knowledge, there are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-8, 10 and 11 are the only claims pending in the above-identified application.

Claims 1-8, 10 and 11 are appealed.

IV. STATUS OF AMENDMENTS

An Amendment was submitted in response to the final rejection on November 26, 2003 but was refused entry.

V. SUMMARY OF INVENTION

The present invention relates to an injection molding method for neutral and acid group-containing (meth)acrylate copolymers, which comprises melting a mixture of a (meth)acrylate copolymer comprising from 40 to 100% by weight of free-radical polymerized C<sub>1</sub>-C<sub>4</sub> alkyl esters of acrylic or methacrylic acid and from 0 to 60% by weight of (meth)acrylate monomers having an anionic group in the alkyl radical, and from 0.1 to 3% by weight of a release agent, along with optional additives and which mixture prior to melting has a content of more than 0.5% by weight of low-boiling constituents with vapor pressure of at least 1.9 bar at 100 °C; devolatilizing the mixture in the thermoplastic state at a temperature of at least 100 °C to lower to not more than 0.5% by weight the content of the low-boiling constituents and injecting the molten and devolatilized mixture into a mold cavity of an injection mold with the temperature of the mold cavity being below the glass transition temperature of the (meth)acrylate copolymer by at least 10 °C, cooling the molten mixture and removing the resultant material from the mold. The devolatilization step may be carried out in an extruder with a devolatilizing section or in an injection molding plant with a vent in the injection molding cylinder. The invention also relates to a molding produced by the above process and to a method of filling the mold of to the present invention with a

pharmaceutical ingredient (See the specification, pages 2 and 3; pages 6-9; page 12 and page 15).

#### VI. ISSUES

The issue in this appeal is as follows: whether or not Claims 1-8, 10 and 11 are unpatentable under 35 U.S.C. § 103(a) over Lehmann et al in view of Vetter et al.

#### VII. GROUPING OF CLAIMS

Claims 1-8, 10 and 11 do not stand or fall together. The patentability of Claim 3 will be argued in a separate paragraph below.

#### VIII. ARGUMENT

(A) Against the Rejection of Claims 1, 2, 4-8, 10 and 11 Under 35 U.S.C. § 103(a) as Unpatentable Over Lehmann et al in View of Vetter et al.

In the final Office Action the Examiner admits that Lehmann et al fails to teach or suggest that the copolymer melt used in the injection molding method of the present claims is devolatilized in a thermoplastic state. The Examiner states in the final Office Action that Vetter et al teaches a method of processing plastic melts in which the plastic is a poly(methyl methacrylate) and the melt is subjected to extrusion to devolatize the melt on page 3 (column 5, line 13 - column 6, line 6 of Vetter et al). The Examiner further states on page 4 of the Final Office Action that Vetter et al teaches a method of forming plastics in which the extrusion step of the process devolatizes the polymer from impurities or unwanted monomeric units as well as water and that it would have been obvious at the time of the invention that extrusion can devolatize the melted polymeric mixture and removes water from the mixture.

However, Vetter et al does not use devolatization to remove impurities or unwanted monomeric units as well as water but clearly indicates in column 3, lines 17-38 and column 5, line 13 through column 6, line 6 that devolatization is used to remove a treatment agent or an unspecified secondary product released during the treatment which is volatile (column 3, lines 17-22) or water may be positively added and the mixture of water and residual monomers devolatized to remove the residual monomers by means of the added water (column 3, lines 29-37) or a mixture of plastic melt and treatment agent may be degassed as set forth in column 5, line 13 through column 6, line 6 to devolatize materials like those discussed in column 3, lines 17-22. Thus, it can be seen that Vetter et al is not directed to the devolatization of untreated poly(methyl methacrylate) polymer, as is the case with the copolymer of the present claims.

Further, the positive addition of water in Vetter et al is different from the situation in the present invention in which low boiling constituents of the mixture of the present claims and devolatization thereof is discussed on pages 11 and 12 of the specification. It is stated therein that the low boiling constituents in the copolymer of the present claims are limited to mainly water absorbed from the moisture present in air or derived from the polymer preparation process. There is no positive addition of water to the composition of the present claims. Although the Examiner argues that the present claims do not exclude the positive addition of water to the process, the present specification on pages 11 and 12 clearly teaches away from the positive addition of water to the mixture used in the process of the present claims and, therefore, the Examiner cannot allege motivation for the addition of a constituent, i.e., water, which is clearly not taught or suggested as being positively added to the mixture used in the process of the present claims. Thus, there is no motivation for the worker of

ordinary skill in the art to incorporate the devolatilization process of Vetter et al into the step of Lehmann et al.

In addition, the mixtures of Vetter et al do not contain a mold release agent, as in the present claims, and the quality requirements for the moldings produced in Vetter et al, i.e., light covers for automotive vehicles disclosed in column 6, lines 53-61, are not comparable to those required for injection molded articles used for pharmaceutical purposes, i.e., capsules, as in the present invention. Therefore, Vetter et al is not combinable with Lehmann et al, because the requirements for the production of injected molded articles in the two references are very different along with the fact that Vetter et al does not teach or suggest a mold release agent, contrary to the claims of the present invention.

Superior results are shown for injection moldings produced by the process of the present claims, as compared to injection moldings produced by processes outside the present claims. Example 1 uses a mold release agent within the amount range of the present claims and produces moldings by the process of the present claims which, after 300 injection molding cycles, produce no deposits on the surface of the mold used. The polished mold surface after 300 injection molding cycles is shiny and metallic, with high gloss. In contrast, in Comparative Example 2 in which the same monomers were used and the same process was carried out as that of Example 1 and very close to Examples 1 and 8 of Lehmann et al, in which there is used a mold release agent in an amount outside the range of the present claims, it was found that after only 14 injection molding cycles, matt areas could be found on the surfaces of the capsules produced. The injection mold was inspected after the 14 injection molding cycles and showed deposit on the surface of the mold. The deposit was analyzed and the presence of glycerol monostearate was detected. Finally, Comparative Example 3 in which the composition of Example 1, including a mold release agent within the amount range

of the present claims, was used, but the process had no devolatilization step, as in the present claims. The injection molding process of Comparative Example 3 with no devolatilization step produced capsules that had surface defects, such as streaks, grooves and uneven areas. Therefore, it is clear that the process of the present claims, which includes a devolatilization step and a mold release agent from 0.1 to 3% by weight, produces molded articles, such as, capsules for pharmaceutical purposes, superior to those produced by a process not including the devolatilization step of the present claims or having a mold release agent outside the percent by weight range of the present claims. Therefore, the claims distinguish over the combination of references.

(B) Against the Rejection of Claim 3 Under 35 U.S.C. § 103(a) As Unpatentable Over Lehmann et al in View of Vetter et al.

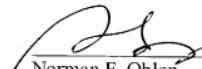
Copolymer a) in Claim 3 positively recites the inclusion of 1-50% by weight of methacrylic acid in the copolymer, which means that the polymer of Claim 3 is an anionic copolymer in contrast to the polymers of Vetter et al, i.e., poly(methyl methacrylate) or poly-(methacrylalkylimide) polymers, which are neutral and not anionic. Therefore, the copolymer of Claim 3 differs significantly from the copolymers of Vetter et al and there is no motivation for the worker of ordinary skill in the art to substitute the polymer of Claim 3 for those of Vetter et al. Claim 3 distinguishes over the combination of references.

Application No. 09/913,720  
Reply to Office Action of August 26, 2003

In view of the preceding arguments, Appellants respectfully request that the Examiner's rejection of Claims 1-8, 10 and 11 be reversed.

Respectfully submitted,

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## APPENDIX

1. An injection moulding process comprising:

A) Melting a mixture comprising

a) a (meth)acrylate copolymer comprising from 40 to 100% by weight of free-radical-polymerized C<sub>1</sub>-C<sub>4</sub>-alkyl esters of acrylic or methacrylic acid and from 0 to 60% by weight of (meth)acrylate monomers having an anionic group in the alkyl radical, and

b) from 0.1 to 3% by weight of a release agent,

and, optionally,

c) from 0 to 50% by weight of a drier,

d) from 0 to 30% by weight of a plasticizer,

e) from 0 to 100% by weight of additives or auxiliaries,

f) from 0 to 100% by weight of an active pharmaceutical ingredient,

g) from 0 to 20% by weight of another polymer or copolymer,

wherein the amounts given for components b) to g) are based on the (meth)acrylate copolymer a), and wherein

the mixture prior to melting has a content of more than 0.5% by weight of low-boiling constituents with vapour pressure of at least 1.9 bar at 120 °C,

B) Devolatilizing the mixture in the thermoplastic state at a temperature of at least 120 °C, thereby lowering to not more than 0.5% by weight the content of the low-boiling constituents with vapour pressure of at least 1.9 bar at 120 °C,

C) Injecting the molten and devolatilized mixture into the mould cavity of an injection mould, the temperature of the mould cavity being below the glass transition temperature of the (meth)acrylate copolymer by at least 10 °C, cooling the molten mixture, and removing the resultant moulding from the mould.

2. The process according to Claim 1, wherein the devolatilizing step B) is carried out by extrusion drying by an extruder with a devolatilizing section, or by an injection moulding plant with a vent in the injection moulding cylinder upstream of the injection mould.
3. The process according to Claim 1, wherein the (meth)acrylate copolymer comprises, as (meth)acrylate monomer having an anionic group in the alkyl radical, from 1 to 50% by weight of methacrylic acid.
4. The process according to Claim 1, wherein the mixture comprises from 0.5 to 25% by weight of plasticizer.
5. An injection moulding produced by a process according to Claim 1.
6. The moulding according to Claim 5, wherein the impact strength to ISO 179 is at least 5 kJ/m<sup>2</sup>.
7. The moulding according to Claim 5, wherein the moulding comprises a capsule, part of a capsule, or part of a dosage unit.
8. The moulding according to Claim 5, wherein the moulding comprises an active pharmaceutical ingredient.
10. A method of filling the moulding according to Claim 5, comprising inserting an active pharmaceutical ingredient therein.

11. The process according to Claim 1, wherein the release agent is from 0.2 to 1% by weight.